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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
|--|-------------|----------------------|---------------------------------|-----------------------------|
| 10/560,894   | 02/13/2007  | Yoshinobu Nakajima   | 283009US0PCT                    | 2360                        |
| 22850  | 7590        | 07/07/2009           |                                 |                             |
| OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.<br>1940 DUKE STREET<br>ALEXANDRIA, VA 22314 |             |                      | EXAMINER<br>MOORE, WALTER A     |                             |
|  |             |                      | ART UNIT<br>1794                | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>07/07/2009 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/560,894 | <b>Applicant(s)</b><br>NAKAJIMA ET AL. |  |
|                              | <b>Examiner</b><br>WALTER MOORE      | <b>Art Unit</b><br>1794                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03292007, 03212006, 12162005</u> .                            | 6) <input type="checkbox"/> Other: ____.                          |

## DETAILED ACTION

### *Specification*

1. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (page 6). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
2. The disclosure is objected to because in Table 1 on page 19 the weight ratio of the enzyme treated yolk is not labeled as a percentage. For example, in Table 1 Example 1 the weight ratio of enzyme treated yolk is listed as 0.44. The weight ratio of the enzyme treated yolk is the weight of antioxidant divided by the weight of the yolk (Specification, p. 10). In Example 1, the weight of the antioxidant (tocopherol) is listed as 0.07 (calculated at 0.06699669, but rounded in table). The net weight of the yolk is listed as 15.22.  $0.066966/15.22$  equals 0.00439928. In no instance will any of the listed weight ratios equal the numbers in Table 1 - unless the weight ratios are actually percentages. Appropriate correction is required.
3. The following table lists the calculations for each example of Table 1.

|   |        |        |        |        |        |        |        |        |        |
|---|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Tocopherol concentration                      | 0.07   | 0.13   | 0.65   | 0.3    | 0.4    | 0.13   | 0.13   | 0.13   | 0.13   |
| Enzyme treated yolk                           | 15.22  | 15.22  | 15.22  | 15.22  | 10.2   | 15.22  | 15.22  | 15.22  | 15.22  |
| Tocopherol concentration /Enzyme treated yolk | 0.0045 | 0.0085 | 0.0427 | 0.0197 | 0.0392 | 0.0085 | 0.0085 | 0.0085 | 0.0085 |

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an acidic oil-in-water emulsified composition, comprising fats and oils comprising 30 wt% or more of diglycerides, an enzyme-treated yolk, and an antioxidant at 1000 to 10000 ppm relative to an oil phase containing the fats and oils, it does not reasonably provide enablement for a weight ratio of 0.4 to 4.5 relative to the net weight of yolk in the enzyme-treated yolk. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

6. The weight ratio of 0.4 to 4.5 cannot be achieved as the invention is disclosed. To calculate the maximum weight ratio of the invention as disclosed, insert the maximum disclosed values of antioxidant (10,000 ppm) and oil (80%), and the least amount of yolk (5%). That calculation results in a weight ratio of 0.16 (calculation:  $[10,000 \text{ ppm} * 80 \text{ (oil)}] / 5 = 0.16$ ). In the alternative, if the antioxidant is dispersed in both the water and oil phases then the maximum weight ratio of the antioxidant to the yolk is 0.19 (calculation:  $[10,000 \text{ ppm} * 95 \text{ (water and oil)}] / 5 \text{ (yolk)} = 0.19$ ). Therefore, a weight ratio of 0.4 to 4.5 cannot be achieved in the invention as disclosed.

7. Please note the value of 95 indicating the amount of oil and water is derived from the concept that if the yolk was 5% of the composition, the oil and water would comprise

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an additional 95% of the composition. The simplification does leave the antioxidant out of the composition. However, ignoring that number only increases the value of the weight ratio. Therefore, discounting the weight of the antioxidant in the composition construes the claims in the light most favorable to the Applicant.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. The weight ratio of 0.4 to 4.5 is indefinite as claimed. As discussed above, the weight ratio in Table 1 is a percentage. Furthermore, inserting the maximum values for the disclosed ranges of antioxidant (10,000 ppm), the percentage of oil (80%), and the least amount of yolk (5%) results in a weight ratio of 0.16 (calculation:  $[10,000 \text{ ppm} * 80]/5 = 0.16$ ). Therefore, it is unclear whether the weight ratio is a percentage or some other measure of a range.

### ***Claim Interpretation***

11. In view of the Objection of the Specification and the 35 USC § 112 rejections, the Examiner is interpreting the weight ratio of antioxidant to yolk as 0.4 to 4.5 percent for the 35 USC § 103 rejections.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-5 and 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai et al., WO 00/78162 A2, in view of Goto et al., USPN 6,139,897.

14. Regarding claim 1, Kawai teaches an acidic (pH 2 to 6, col. 3, ln. 10-11) oil-in-water emulsified composition (p. 1, first paragraph), comprising fats (p. 5, ln. 16-19) and oils (p. 4, second paragraph, ln. 3) comprising 30 wt% or more of diglycerides (p. 5, ln. 8-13) and an enzyme-treated yolk (p. 7, third paragraph) treated with one or more enzymes selected from the group consisting of esterase, lipase, and phospholipase (p. 7, third paragraph).

15. Kawai does not teach the oil-in-water composition comprises an antioxidant at 1000 to 10000 ppm relative to an oil phase containing the fats and oils and at a weight ratio of 0.4 to 4.5 relative to the net weight of yolk in the enzyme-treated yolk.

16. Goto is drawn to an acidic (col. 6, ln. 24) oil-in-water composition (col. 6, ln. 13) comprising diglycerols (col. 2, ln. 63) and phytosterols (col. 6, ln. 20). Goto teaches adding antioxidant in the range of 50 to 2000 ppm (col. 4, ln. 66-67). Goto teaches adding the antioxidant for the purposes of storage stability and flavor stability (col. 4, ln. 67). It would have been obvious to one of ordinary skill in the art at the time of invention to use an antioxidant, as taught in Goto, in the oil-in-water emulsified composition,

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taught in Kawai, to obtain an oil-in-water emulsified composition having an antioxidant because the antioxidant improves storage stability and flavor stability (Goto, col. 4, ln. 67).

17. The examiner notes that adding 2000 ppm of antioxidant, as taught in Goto, to the oil-in-water emulsified composition, taught in Kawai, results in an antioxidant to yolk weight ratio of 0.019, which is 1.9%. See Kawai, Table 2, Example 4 (calculation:  $[2000 \text{ ppm} * 70 \text{ (oil phase)}] / 7.5 \text{ (10\% salt added yolk)} = 0.019$ ).

18. Regarding claims 2, 4, and 8, Kawai teaches the oil-in-water emulsified composition includes an emulsifier such as sorbitan fatty acid ester, polyglycerin fatty acid ester, or sucrose fatty acid ester (p. 6, ln. 16-18).

19. Regarding claims 5, and 9-13, Kawai teaches the oil-in-water emulsified composition comprises a phytosterol (p. 8, second paragraph).

20. Regarding claims 3 and 7, Goto teaches the antioxidant is tocopherol and tocotrienol (col. 5, ln. 3).

21. Claims 6 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai et al., WO 00/78162 A2, in view of Goto et al., USPN 6,139,897, as applied to claims 1-5 and 7-13 above, and further in view of Koike et al., WO 2002/011552.

22. Kawai in view of Goto is relied on as above. Kawai in view of Goto does not teach an oil-in-water emulsified composition wherein the content of trans-unsaturated fatty acids in the diglyceride is 5% or less.

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23. Koike is drawn to an oil/fat composition having a specific glyceride composition (p. 1, ln. 4-5). Koike teaches a diglyceride with 15 to 90 wt. % of its fatty acid constituents comprising omega 3-unsaturated fatty acids. Specific examples include .alpha.-linolenic acid (all cis-9,12,15-octadecatrienoic acid) and stearidonic acid (all cis-6,9,12,15-octadecatetraenoic acid) (bottom p. 4 to top p. 5). Koike teaches the content of the trans-unsaturated fatty acid is preferably 5% or less for health reasons (p. 5, ln. 17-18). Koike highlights various negative health aspects of trans-unsaturated fatty acids (p. 2). It would have been obvious to one of ordinary skill in the art at the time of invention to use diglycerides with a trans-unsaturated fatty acid content of less than 5%, as taught in Koike, in the oil-in-water emulsion composition, taught in Kawai in view of Goto, to obtain an the oil-in-water emulsion composition having diglycerides with a trans-unsaturated fatty acid content of less than 5% because diglycerides with 5% and lower trans-unsaturated fatty acids pose less health risks (Koike, p. 2).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WALTER MOORE whose telephone number is (571) 270-7372. The examiner can normally be reached on Monday-Thursday 9:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/WM/

Walter Moore, Examiner AU 1794

/David R. Sample/

Supervisory Patent Examiner, Art Unit 1794